

Open Comparison Study between Augmentin and Ampicillin-Chloramphenicol in the Treatment of Bronchopneumonia in Children

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ABSTRACT Sixty children under 2 years of age suffering from bronchopneumonia were evaluated for the effectiveness of the treatment. The first group consisted of 30 patients was treated with a single drug, i.e., Augmentin (amoxycillin and clavulanic acid) as a study group. The second group was treated with a combination of ampicillin and chloramphenicol as a control group. The two groups showed good clinical response to the given treatment. Clinical signs and symptoms of bronchopneumonia disappeared within the similar period in both groups, including decrease of fever, disappearance of dyspnea, and diminution or disappearance of rales. The clinical effectiveness in this study, as measured by the disappearance of clinical signs and symptoms, was considered to have a success rate of 82.1% in the study group and 72.2% in control group. [Paediatr Indones 1995; 35:222-226]

Introduction

Bronchopneumonia still constitutes a high mortality and morbidity in children in developing countries including Indonesia. Until 1972, acute respiratory infection had shown a prime morbidity in outpatient clinic in the Department of Child

Health, Cipto Mangunkusumo Hospital, Jakarta. Bacterial identification and sensitivity test are difficult to obtain in pediatric patients. Thoracocentesis and lung puncture as a diagnostic procedure in diagnosing of bronchopneumonia in children are often harmful and difficult to perform. Throat swab culture usually has no correlation with the lower respiratory tract infection.^{3,4} Augmentin is a formula which contains amoxycillin and clavulanic acid, a potent and specific inhibitor for Beta lactamase production. Clavula-

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nic acid has been proven to prevent amoxicillin from destruction of beta lactamase. The reaction which takes place between clavulanic acid and beta lactamase causes a relatively stable complex, and this is the way how the enzyme is inhibited. By this inhibition, the organism which is usually resistant to amoxicillin becomes sensitive.

In the Department of Child Health, Cipto Mangunkusumo Hospital, Jakarta a combination of ampicillin or procain penicillin and chloramphenicol has been the standard treatment of severe hospitalized bronchopneumonia cases. An alternative treatment, Augmentin is chosen for a single therapy in bronchopneumonia cases as it has a broad spectrum antibiotic. The purpose of this study is to evaluate the effectiveness of Augmentin parenteral and orally in the treatment of severe bronchopneumonia in children under 2 years of age comparing with conventional treatment using ampicillin and chloramphenicol.

Methods

The study was carried out between March 1 and October 31, 1987. There were 60 patients from 9 months to 2 years of age with bronchpneumonia who were hospitalized in the Infection Ward of the Department of Child Health, Cipto Mangunkusumo Hospital, Jakarta. They were randomly assigned into study group (30 patients) and control group (30 patients). The study group patients were injected with Augmentin (Aug) intravenously and continued orally, while the control group patients were treated with

standard regimen, i.e., intravenous ampicillin and chloramphenicol (Amp-Chl). Patients receiving Augmentin had been selected for not having any contraindication for the drug, suspicion of *Pseudomonas sp.* as an etiologic factor, and no evidence of renal and liver disease.

All patients were diagnosed clinically and radiologically. Natural history of the disease, side effects, laboratory findings and blood gas analyses before and after treatment were recorded. Bacteriologic examination was not performed because of technical difficulties.

Augmentin was given 30 mg/kg body weight, 3-4 times daily intravenously, followed by oral administration 3 times daily if there was an improvement. Ampicillin was given 100 mg/kg body weight and chloramphenicol 50 mg/kg body weight, 4 times daily intravenously. Supportive treatment such as oxygen was given accordingly; no antipyretic was given.

Clinical evaluation was considered as:

- Excellent, if the clinical signs and symptoms disappeared within 3 days of treatment and the body temperature became normal.
- Good, if the clinical signs and symptoms disappeared in the 4th to 6th day of treatment.
- Fair, if the disappearance of the clinical signs and symptoms took place on the 7th to 10th day of treatment.
- Weak, if the clinical signs and symptoms were not diminished after 10 days of treatment.

Data were collected in a specially designed form, and presented in the form of text and tables, elaborated manually and by using Epi-Info program. For statistical analysis chi-squared test was used; p value of less than 0.05 was considered to be significant.

Results

The clinical characteristics patients in the 2 groups were depicted in Table 1. It shows that the sex ratio, age, and body weight of patients in the 2 groups were similar.

Table 1. The characteristic of Augmentin and Amp-Chl groups.

	Aug	Amp-Chl
No. of cases	30	30
Age	13.8 ± 3.6	14.2 ± 4.6
Body weight	7.96 ± 1.2	8.04 ± 1.6
Sex ratio	13/17	16/14

Table 2 shows the disappearance of fever in the 2 groups. Both in study and control groups, most patients had their temperature normal between day 4 and day 6 of treatment. Statistical analysis showed that there was no different in the 2 groups.

Table 2. The disappearance of the fever in study and control group

Day	Aug	Amp-Chl
1 - 3	9 (30%)	9 (30%)
4 - 6	14 (47%)	13 (43%)
7 - 10	7 (23%)	8 (27%)

χ^2 test; $df=1$; $p > 0.05$

Dyspnea as a leading sign in bronchopneumonia resolved in most cases of the 2 groups in the first 3 days after the initiation of treatment. Overall, there was no significant difference of the disappearance of dyspnea between the study and control groups. See Table 3.

Table 3. The disappearance of dyspnea in study and control group

Day	Aug	Amp-Chl
1 - 3	17 (57%)	17 (57%)
4 - 6	12 (40%)	9 (30%)
7 - 10	1 (3%)	4 (13%)

χ^2 test; $p > 0.05$

The disappearance of pulmonary rales in both groups is presented in Table 4. It is evident that in most cases the rales had disappeared before the 6th day of treatment, and there was no significant difference between both groups as far as the disappearance of dyspnea is concerned.

Table 4. The disappearance of rales in study and control group

Day	Aug	Amp-Chl
1 - 3	4 (13%)	2 (7%)
4 - 6	18 (60%)	15 (50%)
7 - 10	8 (27%)	13 (43%)

χ^2 test; $df=1$; $p > 0.05$

Table 5. The overall success rates in the study and control group

Evaluation	Aug	Amp-Chl
Excellent	10 (33%)	9 (31%)
Good	16 (49%)	13 (41%)
Fair	4 (17%)	8 (28%)
Weak	3 -	2-

Discussion

Up to now, there are rare reports on the use of intravenous Augmentin for the treatment of lower respiratory tract infection in pediatric age group. Jeffries et al.⁷ collected data from the private practicing physicians who had experience in treating pediatric infections with oral Augmentin. Forty-four out of 385 patients in ambulatory treatment were under 2 years of age, almost all of the cases had upper or lower respiratory tract infection. Ninety eight patients with lower respiratory tract infections, i.e., bronchitis, pneumonia and tracheitis were treated with Augmentin. The results showed that 72 patients responded well, 15 showed satisfactory result, and 12 patients were considered unresponsive.

An analysis of side effects indicates that Augmentin has a profile that is similar to amoxicillin, such as diarrhea, nausea, vomiting and skin rash. The clinical effectiveness in adult have been investigated by many authors. Takebe⁵ reported

success rate of 81,1% for acute bronchitis, 62.5% for chronic bronchitis and 72.2% for pneumonia. Graham⁶ reported that 97% of patients with lower respiratory tract infection including bronchitis, pneumonia and bronchiectasis responded to Augmentin. Side effects were found in 20% of cases in the form of mild gastrointestinal disturbances.

This study included 60 children with bronchopneumonia duplex, divided into 2 groups, with the equal number of 30 cases in the study and the control group. The 2 groups showed good clinical result to the treatments. The study and control groups showed that in most patients the clinical signs and symptoms had disappeared within 6 days of treatment. Based on the criteria of evaluation defined before the study, the results of the study were encouraging in both groups. It is recorded that the success rate was 82.1% in the study group and 72% in the control group. Records of side effects indicated that both regimens were well tolerated. Three cases died in the study group, 2 cases in the control group, but all of these cases died due to the severity of the diseases and/or complication which was not correlated with the use of antibiotics.

Summary

The results of this study has encouraged the use of intravenous followed by oral Augmentin in patients with bronchopneumonia. It can be used as an alternative single treatment besides the combination of ampicillin and chloramphenicol which has been used as a standard therapy in the Department of Child Health Cipto Mangunkusumo Hospital.

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References

1. Dawson KP. Respiratory infection in childhood. *J Pediatr Obstet Gynecol* 1983; 25-8.
2. Limson BM. Treatment of pneumonia in childhood. *Mother & Child* 1979;5:17-20.
3. Sutejo R. Past, present and future of pediatrics in Indonesia. The 2nd Asian Congress of Pediatrics 1976; 102-10.
4. Reading C. The biochemistry and mode of action of Augmentin. Proceedings of an International Symposium 1981; 5-21.
5. Takebe K. The evaluation of Augmentin treatment in respiratory tract infections. Proceeding of an International Symposium 1981; 125-37.
6. Graham VAL, Lowes JA, Shaw EJ, Davies RJ. An assesment of the value of Augmentin in the management of respiratory tract infections. Proceeding of an International Symposium 1981; 138-49.
7. Jeffries MG, Rose AJ, Williams HN. An initial assesment of Augmentin for the treatment of pediatric infections in general practice *Brit J Clin Pract* 1981; 61-6.